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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,044	07/08/2003	Paul Andrew Benjes	223505	3936
23460	7590	02/28/2005	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,044

Applicant(s)

BENJES ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,4-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

Claims 1, 4-18 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 4-16, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10-11, 18, fail to recite the specific reagents, solvent and how the process is performed. Therefore, claims 1, 4-16, 18, are indefinite. The claims fail to conform to US patent practice by failing to recite the "positive step(s)" of how the process is performed. A claim must stand alone to define the inventions, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Claims 1, 10-11, 18, are written in functional language and therefore, broader than the enabling disclosure. For example, the claims recite "protecting", "removing/removal", "cyclisation", "preparing" etc. Claim 10 fails to set forth how kifunensine is prepared from formula I while claim 18 fails to set forth what process of kifunensine is improved how the improvement is accomplished. Therefore, claims 1, 4-16, 18, are indefinite. The Claims must recite specific steps as to how one of ordinary skill in the art would perform the "protecting", "cyclisation", "removing/removal", etc. Appropriate correction is required and claim 18 must be deleted to overcome the rejection.

Art Unit: 1626

Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive. Applicant argues that the claims recite specific steps of how "protecting", "cyclisation", "removing/removal", are performed. This is not persuasive for reasons set forth above. Applicant also contends that the specification exemplifies how "protecting", "cyclisation", "removing/removal", etc. are performed. This is not persuasive because the claims as written are broader than the enabling disclosure in the specification. While the claims are drawn to all/any process of performing "protecting", "cyclisation", "removing/removal", etc the specification provides specific ways of performing the process. Therefore, the claims, as written, lack adequate support in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayakiri et al., Chem. Bull. Vol. 39, No. 6 (1991), pages 1392-1396, (Kayakiri et al., I) individually or in view of Kayakiri et al., Tetrahedron Let, Vol. 31, No. 2 (1990), pages 225-226 (Kayakiri et al., II).

Applicant claims a process of making kifunensine from compounds of formula I, and a process of making compounds of formula I comprising steps (a) to (d) set forth in claim 1, steps (e) to (i) set forth in claim 11 and steps (a) to (g) in claim 17. In preferred embodiment, applicant claims specific reagents and how the process is performed. In other embodiment, applicant changes the sequence of the reaction steps or combines steps/reagents from both prior arts – selective combination.

Art Unit: 1626

Determination of the scope and content of the prior art (MPEP §2141.01)

Kayakiri et al., teach a similar process of making kifunensine from compounds of formula I, and a process of making compounds of formula I. Kayakiri et al., teach all the instantly claimed steps, the reagents and reaction conditions. See pages 1392-1394, charts 1-7 and the experimental sections on pages 1394-1396 (first prior art) and pages 225-226 of second prior art.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Kayakiri et al., is that applicant changes the sequential order of the reaction steps or combines steps/reagents from both prior arts - selective combination.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

Selective combination of prior art(s) teaching is prima facie obvious. There is no indication of an interaction between the steps such that one of ordinary skill in the art would have any doubts that the selective combinations could not be made. *In re Mostovych*, 144 USPQ 38 (CCPA, 1964). Therefore, the instant invention is prima facie obvious from the teachings of the prior art of Kayakiri et al. One of ordinary skill in the art would have known to claim the workup of the waste at the time the invention was made. The motivation is to claim a new process of making kifunensine.

Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive. In the claims applicant added N-acetyl as the protecting group at position 6, and contends that the prior art use N-oxamoyl protecting group. Applicant asserts that N-acetyl allows for a large-scale production. This is not persuasive because using an analogous starting material in a well-known process is prima facie obvious. *In re Durden*, 226 USPQ 359 (1985). In the instant N-acetyl and N-oxamoyl are analogous starting materials.

Art Unit: 1626

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

February 22, 2005